Protocol Number:
FDA **257A.**

Title:
Study of the Safety and Effects of Two Doses of SPC3, Administered Daily Intravenously in HIV-1 Seropositive Patients. (FDA DISCLAIMER: The FDA encourages the inclusion of females of childbearing potential in study protocols, but the sponsor of this protocol specifically excludes females of childbearing potential from this study and includes only females who are sterile. Any questions about these inclusion/exclusion criteria should be directed to the study's contact person.).

Protocol Summary:
Purpose:
To assess the effects of two doses of synthetic peptide construction 3 (SPC3) on HIV-1 plasma levels (as measured by RNA PCR Amplicor) and on lymphocyte subsets in patients with initial viral load above 10000 copies/ml. To study the safety of SPC3 and the kinetics of HIV-1 plasma level changes.
Methodology:
The first five patients receive SPC3 daily for 3 weeks. If that dose is tolerated, the dose is increased and given to the next 5 patients for 3 weeks. The remaining ten patients receive a dose of SPC3 based on response to the previous two dose levels. Patients are followed through day 28.

Study Intent:
Drug efficacy, Drug safety, Pharmacokinetics.

Study Design:
Dose-Response Design.

Protocol Status:
No longer recruiting (990409).

Duration of Patient on Study:
4 weeks.

Inclusion Specification Criteria:
Patients must have:
1. HIV seropositive for at least 6 months.
2. CD4 >= 100 cells/mm3.
3. HIV RNA PCR (Amplicor) > 10000 copies/ml.
4. No significant active opportunistic infection or tumor at study entry.
FDA DISCLAIMER: The FDA encourages the inclusion of females of childbearing potential in study protocols, but the sponsor of this protocol specifically excludes females of childbearing potential from this study and includes only females who are sterile. Any questions about these inclusion/exclusion criteria should be directed to the study's contact person.

CD4 (T4 Cell) Count:
>= 100 cells/mm3 (100 - 200 - 300 - 400 - 500 - 600 - 700 - 800 - plus).

Inclusion Age:
Greater than or equal to 18 years less than or equal to 65 years.

Inclusion Sex:
Both.

Inclusion Reproductive Specification:
Not breast-feeding Postmenopausal or permanently sterile because of tubal ligation, hysterectomy, or oophorectomy.

Inclusion Prior Medication:

Allowed: Prior antiretrovirals.

Inclusion Concurrent Medication:
Allowed: Antiretrovirals provided regimen has been stable for at least 6 weeks prior to study screening.

Exclusion Specification Criteria:
Patients with the following prior condition are excluded:
History of relevant drug hypersensitivity.

Exclusion Reproductive Specification:
Future reproduction Breast-feeding.

Exclusion Prior Medication:
Excluded: Investigational drug within the past 4 weeks.

Exclusion Concurrent Medication:
Excluded: Any drug that may interact with SPC3 (e.g., suramin).

Exclusion Co-Existing Conditions or Diseases:
Patients with the following conditions are excluded:
Inability to communicate with investigator or deemed likely to be noncompliant on study.

Generic Drug Name:
Drug 1: Synthetic Peptide Construction 3. Antiretroviral.

Dosage Schedule:
Drug 1: 20 or 40 mg daily for 3 weeks.

Duration of Drug Administration:
3 weeks.